

**REMARKS**

In response to the office action of November 14, 2007, Applicant cancels claim 5 and adds new claims 10 to 18 to more particularly point out and distinctly claim desirable embodiments. After amendment, claims 4, and 6-18 are pending, including a fourth and fifth independent claim. Payment is made for the two extra independent claims. Reconsideration and allowance respectfully are requested.

Claim 4 has been amended to recite “more than 95% homologous to SEQ ID NO: 1.” This language is supported by extensive disclosure of allelic forms of the recited p2y9 protein in paragraph 0013. A comparison of the sequences provided in this paragraph show a homology that is greater than 95%. Therefore this recitation is supported by paragraph 0013. Sequence homology comparisons are supported by Fig. 1 (which compares homologies in 2 dimensional placement) and also by for example paragraph 0010, which refers to comparisons of “higher degree of sequence homology” with lower.

Claim 6 has been amended to remove unnecessary words.

Claim 7 has been re-worded to make this dependent on claim 4.

New claim 10 recites the same language as claim 4 but omits details of sequence homology.

New claim 11 adds a step of adding LPA for testing, and is supported by examples that describe adding LPA.

New claim 12 recites the same elements as originally filed claim 5.

New claim 13 recites “SEQ ID NO: 1 or an allelic variant thereof” and is supported by allelic variants that are presented in paragraph 0013.

New claim 14 recites quantitation of LPA and is supported by the specification throughout. Fig 6 – 13 and more, for example show quantity of lipid versus effects on the cell mediated by the p2y2 protein.

New claim 15 includes the recitation of amended claim 4 and also content from paragraph 0004.

New claim 16 contains the recitation of amended claim 4 and new claim 14.

New claim 17 contains the elements of amended claim 7.

New claim 18 includes “further screened for effects on carcinoma cell invasion” and is supported by originally filed claim 8.

Accordingly, new matter has not been introduced via amendment.

**Rejection Based on 35 U.S.C. §112 Written Description**

Claims 4, 5, and 7-9 have been rejected on alleged written description grounds under 35 U.S.C. §112, first paragraph, on page 2-3 of the office action. The rejection is respectfully traversed.

The Examiner argues (page 3 bottom middle) that “[t]he claims are drawn to a genus of p2y2 proteins.” However, the claims recite the “G protein-coupled protein p2y2” and the p2y2 protein is not a large genus but is an art recognized species of protein. As evinced by attached Appendix A (catalog entry for US Biological), skilled artisans confidently buy and sell reagents that recognize the p2y2 protein. There is no scientific evidence of multiple species of a p2y2 genus. Quite the contrary, as evinced by Appendix B (a prestigious JBC paper and a list of many peer reviewed articles that cite this paper), there is one protein “identified” as p2y2. Not a genus.

The species of protein termed “p2y2” is well characterized as a single protein with an usually tight range of homology among allelic variants. In fact, paragraph 0013 of the specification cites known sequence information of this single species of protein. The cited art was specifically incorporated by reference because space constraints precluded adding all of the allelic variants and evidence of biochemical functioning etc. within the present application. The variability of allelic members known for this species of protein, as can be seen in the papers of paragraph 0013 is surprisingly small.

Applicant has reviewed the variability of all known p2y2 variants cited in paragraph 0013 and provide this summary of the allelic variants that are described within the specification itself (via the incorporation by reference statement) as Appendix C. Appendix C shows alignments in comparison with “p2y9” in Fig. 18, which belong to the same PAF receptor family. As seen in Alignment 1, “p2y9” is a very unique receptor protein that exhibits a very high homology among the known allelic forms. These are allelic forms and share the same basic properties.

The allelic forms of the single protein known as "p2y2" and described in the 24 incorporated references have been compared. The sequence identity of each of the amino acid sequences in these documents is calculated to be about 96 to 99%. This disclosure thus supports a written description for "greater than 95% sequence homology" to SEQ ID NO: 1. Applicant notes that this is a high homology of forms for the same species of protein and that another form of "p2y2" that is 5% or more different in sequence is not known.

Accordingly, in view of the scientific acceptance of p2y2 as a single protein and not a genus of different functional types, as well as the extensive evidence from 24 documents of very small differences among discovered allelic forms, applicant requests removal of this rejection.

#### **Rejection Based on 35 U.S.C. §112 Indefiniteness**

Claims 4-9 are rejected on alleged indefiniteness grounds under 35 U.S.C. §112, second paragraph, on page 4-5 of the office action. The rejection is respectfully traversed.

#### **Claims 4-9 (bottom of page 5 of the office action)**

These claims are rejected as reciting the protein name "p2y9." However, this name was selected by the scientific community to represent a particular species of protein and a government agency cannot change this meaning or interpret this meaning differently without cause.

As evinced by attached Appendix A (catalog entry for US Biological), skilled artisans confidently buy and sell reagents that recognize the p2y2 protein. There is no scientific evidence of multiple different types of protein that are called p2y2 genus. Quite the contrary, as evinced by Appendix B (a prestigious JBC paper and a list of many peer reviewed articles that cite this paper), there is one protein "identified" as p2y2. The specification already provides further structure for this protein by incorporating (paragraph 0013) a number of very homologous sequences by reference. Still further, a preferred allelic form primary structure is given by the identifier "SEQ ID NO: 1."

Applicant has reviewed the variability of known p2y2 variants cited in paragraph 0013 and provided by incorporation, specific allelic variants within the specification itself. For convenience a comparison of the sequences is provided as Appendix C. Appendix C shows alignments in comparison with "p2y9" in Fig. 18, which belong to the same PAF receptor family. As seen in Alignment 1, "p2y9" is a very unique receptor protein that exhibits a very high homology among the known allelic forms. This is proof that in addition to scientific acceptance of this protein name for a single species, skilled artisans have and can continue to confidently look for, find, and use a single form of protein that differs only by natural allelic variability. These closely related allelic forms share the same basic properties of a single protein. Applicant further notes that no evidence of different proteins that share the same name has been presented, to counterbalance the extensive consensus among skilled artisans that this name refers only to one protein.

Accordingly, in view of the scientific acceptance of p2y2 as a single protein with known properties and primary structure, as well as the extensive evidence from 24 documents of very small differences among discovered allelic forms, applicant requests removal of this rejection.

Claim 4 (top of page 6 of the office action)

Claim 4 recites "substantially represented by SEQ ID NO:1." This recitation means the particular cited sequence and also close homologous forms of the sequence. In response, applicants have amended claim 4 to more distinctly recite "wherein the p2y2 protein comprises an amino acid sequence that is more than 95% homologous with SEQ ID NO:1." Support for the 95% homology value comes from the numerous allelic sequences that are present in the specification via the incorporation by reference statement of paragraph 0013, and which are summarized now in Appendix C.

Support for the "more than 95% homology" term comes from the disclosure itself. The courts (Court of Appeals for the Federal Circuit) specifically allow numerical terms that describe or summarize this kind of chemical conclusion in claim language. See for example *Abbott Laboratories v. Torpharm Inc.*, 300 F.3d 1367, 63 USPQ2d 1929 (Fed. Cir. 2002), copy attached as Appendix D. In *Abbott*, the court allowed claims that recited an oligomer having "about 4 to 6

acid/salt subunits." This numerical claim element was not in Abbott's filed application but was added after Abbott submitted test data to the PTO showing that the "original disclosure of divalproex sodium inherently disclosed the numerical limitations." In the present case, the actual data (homology percentage for numerous allelic forms of p2y2) is not only inherent in the specification itself but actually exists as written information, via the incorporation by reference statement. The specification literally teaches known allelic forms, within the incorporated art and which have sequence homologies that are evident to any one interested in making the comparison.

Accordingly, withdrawal of the rejection and allowance of the new claim respectfully is requested.

Claims 4-9

On page 5 of the office action, claims 4-9 were rejected as not listing suitable steps for a process claim. Claim 4 has been amended and now states more than one step.

Reconsideration and withdrawal of the rejections respectfully are requested.

The Examiner cordially is invited to contact the undersigned if another telephonic conference can advance this case.

Dated: February 14, 2008

Respectfully submitted,

By \_\_\_\_\_  
Brian K. Dutton

Registration No.: 47,255  
RADER, FISHMAN & GRAUER PLLC  
Correspondence Customer Number: 23353  
Attorney for Applicant